K073248

DEC 1 2 2007

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

ATTACHMENT 1
510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2555 Davie Road, Fort Lauderdale, FL, 33317
Phone number:	954-927-2044 x. 605
Fax number:	954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	November 16, 2007
Cleared Device Trade Name:	MAKO Surgical Unicondylar Knee System
Modified Device Trade Name:	MAKO Surgical Unicondylar Knee System, Additional Components
Common Name:	Unicondylar knee
Classification Name:	Class II
Classification #:	21 CFR 888.3520, Product Code: HSX

Substantial Equivalence Claimed To: MAKO Surgical Unicondylar Knee System as described in MAKO Surgical Corp.'s K060017. The modification as described in this submission is shown to be substantially equivalent to the previously cleared system. As required by risk analysis, all verification and validation activities performed to date by designated individuals and the results demonstrated substantial equivalence.

Description and Summary of Technological Characteristics: This device consists of an asymmetrical cast CoCr distal femoral component and a symmetrical ultra-high molecular weight polyethylene tibial resurfacing component. These components are intended for cemented, one-time use only.

The femoral components are available in five sizes (1 through 5) and there is a left and right component for each size. There are five sizes of tibial components and each size is available in three thicknesses designated as 6.5mm, 7.5mm and 8.5mm. The thinnest section of the 6.5mm component is 6.0mm.

The additional components that are the subject of this Special 510(k) submission are the tibial inserts and baseplates. These components are to be used with the femoral components of the MAKO Surgical Unicondylar Knee System (K060017). The previously cleared device is an "inlay" designed unicondylar system where the polyethylene component sits inside the tibial cavity. The device described in this submission adds the "onlay" designed unicondylar components which sit on the tibial ridge.

Intended Use/Indications for Use : The MAKO Surgical Unicondylar Knee System, Additional Components is a single use device intended for cemented reconstruction of the medial or lateral femur and corresponding tibial surface of moderately disabled and/or painful knee resulting from osteoarthritis, traumatic arthritis provided there is evidence of sufficient bone to seat the implant. Indications for use include moderate joint impairment from painful arthritis (osteo and/or post-traumatic), and as an alternative to tibial osteotomy in patients with unicompartmental arthritis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

MAKO Surgical Corp.
% Mr. William F. Tapia
Vice President, RA/QA/CA
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K073248
Trade/Device Name: MAKO Surgical Unicondylar Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: November 16, 2007
Received: November 19, 2007

Dear Mr. Tapia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAKO
SURGICAL CORP

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K073208

Device Name: MAKO Surgical Unicondylar Knee System, Additional Components

Indications for Use:

The MAKO Surgical Unicondylar Knee System, Additional Components is a single use device intended for cemented reconstruction of the medial or lateral femur and corresponding tibial surface of moderately disabled and/or painful knee resulting from osteoarthritis, traumatic arthritis provided there is evidence of sufficient bone to seat the implant. Indications for use include moderate joint impairment from painful arthritis (osteo and/or post-traumatic), and as an alternative to tibial osteotomy in patients with unicompartmental arthritis.

Prescription Use ___X___ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehl

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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